



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,736	03/30/2001	Kevin M. Murphy	032737-002	4771

21839 7590 12/15/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

KALINOWSKI, ALEXANDER G

ART UNIT	PAPER NUMBER
----------	--------------

3626

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,736

Applicant(s)

MURPHY ET AL.

Examiner

Alexander Kalinowski

Art Unit

3626

MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-18 are presented for examination.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed was filed more than one year prior to the instant application. Therefore, claim for priority to the provisional application is denied.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1- 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the instant claims fail to recite the use of any type of technology (e.g. computer system) within the recited steps of the claimed method of matching clinical trials to qualified individuals. The recited steps constitute an idea on how to store clinical trial information, determine if the individuals are qualified for one or more clinical trials and presenting qualified individuals with information for the clinical trials they qualified for.

Mere intended or nominal use of a component, albeit within the technological arts, does not confer statutory subject matter to an otherwise abstract idea if the component does not apply, involve, use, or advance the underlying process.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case the claimed method recites steps for matching clinical trials to qualified individuals.

Although the claimed invention produces a useful, concrete and tangible result, since the claimed invention as a whole is not within the technological arts, as explained above, claims 1-12 are deemed to be directed to non statutory subject matter. The Examiner suggests adding language to the body independent claims that indicates that at least some of the steps are carried out through the use of technology (i.e. computer, data processor).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3626

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Pub.

No. 2002/0099570 A1, Knight.

As to claims 1, 7, and 13 Knight discloses A method for matching specific clinical trials to qualified individuals (paragraph 50), comprising the steps of:
storing criteria for a plurality of clinical trials, where each clinical trial describes a course of treatment for a particular illness or disease Fig. 9);
obtaining information from a user (paragraph 72);
determining whether the user is qualified for one or more clinical trials by comparing the obtained information with the stored criteria (paragraphs 71 and 73); and
presenting the user with information regarding the clinical trials for which it was determined the user was qualified paragraph 73).

As to claims 2 and 8, Knight discloses The method of claim 1 wherein the step of obtaining information includes an initial assessment used in determining the qualification of the user for a particular clinical trial (Fig. 1 and paragraph 71).

As to claims 3 and 9, Knight discloses The method of claim 1 further including the step of storing specific assessment questions for each particular disease and trial, and wherein these questions are presented to the user subsequent to answering initial assessment questions (paragraph 70).

As to claims 4 and 10, Knight discloses The method of claim 1 further includes the step of obtaining clinical trial information from clinical trial sponsors (paragraph 63).

As to claims 5 and 11, Knight discloses The method of claim 2 further including storing the responses to the assessment questions (paragraph 68).

As to claims 6 and 12, Knight discloses The method of claim 1 further including receiving new clinical trials wherein the user is notified of the new clinical trial for which the user is determined to be a possible candidate (paragraphs 131 and 134).

As to claim 14, Knight discloses The system of claim 13 further comprising a relational database that stores information relating to at least one of user information, clinical trials, assessment questions, and clinical trial matches (Fig. 30).

As to claim 15, Knight discloses The system of claim 13 wherein the system is a web based system (paragraph 57).

As to claim 16, Knight discloses The system of claim 13 wherein the system is capable of integrating into other health care related systems (paragraph 127).

As to claim 17, Knight discloses The system of claim 13 wherein information for matching a user to a clinical trial is obtained from a series of assessment questions presented to the user (Fig. 1).

As to claim 18, Knight discloses The system of claim 17 wherein said questions contained predefined answers that identify conditions for inclusion or exclusion from a specific trial (Fig. 4-7).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- a. Pub. No. 2002/0002474 A1 discloses selecting and recruiting subjects for clinical trials.
 - b. Pub. No. 2002/0077853 discloses a system for selecting clinical trials.
 - c. "System makes it easier to link patients to clinical trials" discloses a clinical trials patient matching system
 - d. "Tvisions builds a site for oncology researchers and their clinical trials" discloses matching patients with clinical trials.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

Application/Control Number: 09/820,736

Art Unit: 3626

 Page 7

Alexander Kalinowski

Primary Examiner

Art Unit 3626

12/11/04